PATENT & Express Mail Label No. Dated:

Docket No.: 02521/0200066-US0

(PATENT)

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Provisional Application of:	
Michael Machman et al	

Michael Moshman et al.

Application No.: 10/776,333

Filed: February 10, 2004

For: CONTROLLED RELEASE

FORMULATIONS

Art Unit: N/A

Examiner: Not Yet Assigned

INFORMATION DISCLOSURE STATEMENT (IDS)

Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450

Dear Sir:

Pursuant to 37 CFR 1.56, 1.97 and 1.98, the attention of the Patent and Trademark Office is hereby directed to the references listed on the attached PTO/SB/08. It is respectfully requested that the information be expressly considered during the prosecution of this application, and that the references be made of record therein and appear among the "References Cited" on any patent to issue therefrom.

This Information Disclosure Statement is filed before the mailing date of a first Office Action on the merits as far as is known to the undersigned (37 CFR 1.97(b)(3)).

A copy of each document on the PTO/SB/08 is attached.

The Commissioner is authorized to charge any deficiency of up to \$300.00 or credit any excess in this fee to Deposit Account No. 04-0100.

Dated: May 7, 2004

Respectfully submitted,

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PTO/SB/08a/b (08-03)
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Substitute for form 1449A/B/PTO		Complete if Known			
				Application Number	10/776,333
INFORMATION DISCLOSURE				Filing Date	February 10, 2004
S	STATEMENT BY APPLICANT			First Named Inventor	Michael Moshman
				Art Unit	Not Yet Assigned
(Use as many sheets as necessary)			s necessary)	Examiner Name	Not Yet Assigned
Sheet	1	of	1	Attorney Docket Number	02521/0200066-US0

	U.S. PATENT DOCUMENTS							
Examiner	Cite	Document Number	Publication Date	Name of Patentee or	Pages, Columns, Lines, Where			
Initials*	No.1	Number-Kind Code ² (if known)		Applicant of Cited Document	Relevant Passages or Relevant Figures Appear			
	1	US-5,629,011	05/13/97	Illum				
	2	US-5,840,341	11/24/98	Watts et al.				
	3	US-5,897,858	04/27/99	Haslwanter et al.				
	4	US-6,225,343 B1	05/01/01	Behl et al.				
	5	US-6,261,539 B1	07/17/01	Adjei et al.				
	6	US-6,387,917	05/14/02	Illum et al.				
-	7	US-6,451,848 B1	09/17/02	Behl et al.				
	8	US-6,495,120 B2	12/17/02	McCoy et al.				
	9	US-6,677,346 B1	01/13/04	Achari et al.				

	FOREIGN PATENT DOCUMENTS							
Examiner Initials*	Cite No.1	Foreign Patent Document Country Code ³ -Number ⁴ -Kind Code ⁵ (<i>if known</i>)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T ⁶		

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	NON PATENT LITERATURE DOCUMENTS					
Examiner Initials	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ²			
	10	ASPDEN, T. et al., The effect of Chronic Nalal Application of Chitosan Solutions on Cilia Beat Frequency in Guinea Pigs; Intl. J. of Pharm., 153 :137-146 (1997).				
	11	ASPDEN, T. et al., Chitosan as a Nasal Delivery System: The Effect of Chitosan Solutions on <i>In Vitro</i> and <i>In Vivo</i> Mucociliary Transport Rates in Human Turbinates and Volunteers; J. Pharm. Sci., 86 :509-513 (1997).				
	12	ILLUM, L. et al., Nasal Administration of Morphine-6-Glucuronide in Sheep A Pharmacokinetic Study, Biopharm. & Drug Depos., 17:717-724 (1996).				
	13	KAIKO, R. et al., A Bioequivalence Study of Oral Controlled-Release Morphine Using Naltrexone Blockade; J. Clin. Pharmacol., 35(5) :449-504 (1995).				
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				Art Unit	Not Yet Assigned	
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Sheet	2	of	1	Attorney Docket Number	02521/0200066-US0	

15	HOUDE, R.W. et al., Clinical measurement of pain. In: de Stevens G, ed. Analgesics. New York: Academic Press, 77-122, 1965.	
16	INTURRISI, C.E., Pharmacokinetic-Pharmacodynamic (PK-PD) Relationships of Opioid Analgesics, In: Chapman C.R. and Foley K.M., eds. Current and Emerging Issues in Cancer Pain: Research and Practice. Philadelphia-New York: Lipincott-Raven, 1993, Chapter 12, pages 185-191.	
17	OSBORNE, R. et al., Morphine and metabolic behavior after different routes of administration: Demonstration of the importance of the active metabolite morphine-6-glucuronide, Clin Pharmacol Ther., 47:12-19, 1990.	
18	PASTERNAK, G.W., Progress in Opiate Pharmacology. In: Chapman C.R. and Foley K.M., eds. Current and Emerging Issues in Cancer Pain: Research and Practice. Philadelphia-New York: Lipincott-Raven, 1993, Chapter 8, pages 113-126.	

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Information Disclosure Statement (2 pages); PTO/SB/08 (2 Pages); Copies of 18 cited references; and Return Postcard.